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EXAMINER

BRUNOVSKIS, P

| ART UNIT | PAPER NUMBER |
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1632

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DATE MAILED:

12/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/155,452

Applicant(s)
Borts et al.

Examiner
Peter Brunovskis

Group Art Unit
1632



☒ Responsive to communication(s) filed on Aug 29, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 11-22 is/are pending in the application

Of the above, claim(s) 14, 15, and 18-20 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 11-13, 16, 17, 21, and 22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The response filed 8/29/00 has been entered. Cancellation of claims 1-10 and entry of new claims 11-22 is acknowledged. Claims 11-22 are pending in the instant application. Applicant's arguments filed 8/29/00 will only be considered to the extent that they apply to the pending claims; arguments directed to any other subject matter is considered moot.

Claims 14, 15, and 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13, 16, 17, and 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 (and dependent claims) is indefinite because it is not clear how the method steps relate back to a "process for the meiotic recombination *in vivo* of ...of base mismatches" since the method steps recite "manipulating...and culturing [said] eukaryotic cells under conditions to result

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in the meiotic recombination *in vivo*” without reciting how the *in vitro* steps and the *in vivo* result are connected or how the result *in vivo* result is connected to animals or a processes for making an animal species in accordance with the elected invention. Because of this failure, the new language reciting the phrase, “to result in the meiotic recombination *in vivo* of said partially homologous DNA sequences” does not obviate the previous rejection as asserted in the response (p. 7) inasmuch as the new language fails to “clearly specify” how the “culturing conditions” are defined in the newly recited *in vivo* context, nor does the new language make clear how the methods or processes are either applicable or well known and understood to one skilled in the art in the context of animals or animal cells.

Claim 12 is indefinite in its recitation of the phrase “hybrid genes and their coded proteins”, since this phrase lack antecedent basis in the base claim and it is unclear how or in what way the “hybrid genes” are utilized in the process to which the claim is directed (i.e. cl. 11) or what temporal context applies to “forming and/or isolating” within that process. The claim is also indefinite in its recitation of “and/or”, since it is unclear whether the claim requires forming isolated hybrid genes, isolating hybrid genes, or some combination thereof. Further, the claim is indefinite in its recitation of “genes” in the context of the claim. Applicant's arguments filed 8/29/00 have been fully considered but they are not persuasive. Applicants assert that the term “genes” is a well understood term in biotechnology, but fail to address the details raised in the previous rejection or provide one of skill in the art a basis for determining the metes and bounds of this claim as it relates to “genes”.

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Claim 13 recites the limitation "wherein said eukaryotic cells are formed" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 is indefinite because it is not clear how the method steps relate back to a "process for the meiotic recombination *in vivo* of ...of base mismatches" since the method steps recite "form[ation] of cells" and mixing of cells to form diploids how the additional steps recited in claim 13 relate to the process according to claim 11 or to animals or processes for making animal species in accordance with the elected invention.

Claim 13 and 22 are indefinite in their recitation of the phrase, "by having up to 30% base mismatches with said first DNA sequence" since it is unclear what is meant by "by having" in this context or how mixing the "second group of eukaryotic cells...[presumably] having up to 30% base mismatches in claim 13 relates to "[a] process for the meiotic recombination *in vivo* of ...having up to 30% of base mismatches" as recited in base claim 11.

Claim 16 is indefinite because it is not clear how the process steps recited in claim 11 relate to the limitations recited in claim 16 or, for example, whether the additional limitations recited in claim 16 are performed prior to, or after, the "manipulat[ion]" step.

Claim 17 is indefinite because it is not clear how the process steps recited in claim 16 relate to the limitations recited in claim 16 or which eukaryotic cells are being referred to--the eukaryotic cells prior to, or after, the "manipulat[ion]" step.

Claim 22 is indefinite in its recitation of the phrase "culturing the mixture under conditions to result in the meiotic recombination *in vivo* of said partially homologous DNA sequences"

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because it is unclear how the *in vitro* culture steps and the *in vivo* recombination result are connected or how the *in vivo* recombination result is connected to animals or processes for making animal species in accordance with the elected invention. In addition, it is unclear what is meant by "hybrid" in the context of the claim or how the eukaryotic cells are recovered from "said hybrid eukaryotic specie", particularly since there is no recitation of a "hybrid eukaryotic specie" in any of the method steps.

Claim 22 recites the limitation "the mixture" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claims 11-13, 16, 17, and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

The rejected claims constitute new matter not supported by the instant application. Newly entered claims 11-13, 16, 17, and 20-21 describe new methods or method steps that are not described in the specification, particularly in the context of the elected invention which is drawn to animals. There is no evidence that Applicants envisioned or were in possession of any of the methods drawn to animals recited in the rejected claims comprising culturing cells to result in

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meiotic recombination in animals *in vivo*. Furthermore, to the extent that the claimed processes are not described in the specification in the context of animals, it has failed to describe how to make or use them; one cannot make or use something that was not described.

Claim 11-13, 16, 17, and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the previously recited claims, except for claim 3, none of the other claims recited any method steps drawn explicitly drawn to animals or containing *in vivo* method steps. The newly amended (and rejected) claims recite methods comprising manipulating and culturing cells “to result in the meiotic recombination *in vivo* of said partially homologous DNA sequences”. However, the specification does not provide any guidance for one of skill in the art teaching how to achieve meiotic recombination in animals *in vivo*, how to form or use hybrid genes, how to form or use animal cell diploids, how to create animal cells with defective enzymatic mismatch repair systems or containing missing or defective animal mutL or mutS homologs, or how to use animal germ cells for *in vivo* meiotic recombination commensurate with the claimed subject matter. The specification does not provide any specific examples of these *in vivo* methods or processes therein in the context of the newly amended claims.

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Applicant's arguments filed 8/29/00 have been fully considered but they are not persuasive. Applicants argue that rewriting new claim 13 from original claim 3 by deleting the phrase "making hybrid eukaryotic species" makes the previous rejection "no longer sustainable" (p. 7) without explaining how this change obviates the rejection. Newly entered claim 13 recites an *in vivo* meiotic recombination step that was not clearly recited in original claim 3; however, the specification does not provide guidance teaching how this step is performed or how one is to use the animal or the cells created from this step.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

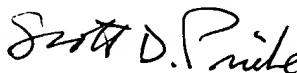
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Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Brunovskis whose telephone number is (703) 305-2471. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda can be reached at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Patent Analyst, Patsy Zimmerman whose telephone number is (703) 308-8338.

Peter Brunovskis, Ph.D.
Patent Examiner
Art Unit 1632


SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER